MENS ROGAINE UNSCENTED FORMULA- minoxidil aerosol, foam Johnson & Johnson Healthcare Products, Division of McNEIL-PPC, Inc.

Men's Rogaine 5% Minoxidil Topical Foam Unscented

Drug Facts

Active ingredient

Minoxidil 5% w/w (without propellant)

Purpose

Hair regrowth treatment for men

Use

to regrow hair on the top of the scalp (vertex only, see pictures on side of this carton)

Warnings

For external use only. For use by men only.

Extremely Flammable: Avoid fire, flame, or smoking during and immediately following application.

Do not use if

- you are a woman
- your amount of hair loss is different than that shown on side of this carton or your hair loss is on the front of the scalp. 5% minoxidil topical foam is not intended for frontal baldness or receding hairline.
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- you do not know the reason for your hair loss
- you are under 18 years of age. Do not use on babies and children.
- your scalp is red, inflamed, infected, irritated, or painful
- you use other medicines on the scalp

Ask a doctor before use if you have heart disease

When using this product

- do not apply on other parts of the body
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some people have experienced changes in hair color and/or texture
- it takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results.
- the amount of hair regrowth is different for each person. This product will not work for all men.

Stop use and ask a doctor if

- chest pain, rapid heartbeat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs

- unwanted facial hair growth occurs
- you do not see hair regrowth in 4 months

May be harmful if used when pregnant or breast-feeding.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply half a capful 2 times a day to the scalp in the hair loss area
- massage into scalp with fingers, then wash hands well
- see enclosed booklet for complete directions on how to use
- using more or more often will not improve results
- continued use is necessary to increase and keep your hair regrowth or hair loss will begin again

Other information

- hair growth has been shown in a clinical study of men (mostly white) aged 18-49 years who used it for 4 months
- see hair loss pictures on right
- before use, read all information on package and enclosed booklet
- keep the package. It contains important information.
- store at controlled room temperature 20° to 25° C (68° to 77° F)
- contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120° F (49° C).

Inactive ingredients

butane, butylated hydroxytoluene, cetyl alcohol, citric acid, glycerin, isobutane, lactic acid, polysorbate 60, propane, purified water, SD alcohol 40-B, stearyl alcohol

Questions?

- call toll-free 800-ROGAINE or 215-273-8755 (collect)
- visit www. rogaine.com

PRINCIPAL DISPLAY PANEL - 60 g Can Carton

NEW

LOOK

#1 DERMATOLOGIST RECOMMENDED BRAND

MEN'S

Rogaine[®]

5% MINOXIDIL TOPICAL AEROSOL HAIR REGROWTH TREATMENT

REVITALIZES HAIR FOLLICLES EASY-TO-USE

FOAM

CLINICALLY PROVEN TO HELP REGROW HAIR

UNSCENTED

Not For Use By Women

Three Month Supply – Three 60 g (2.11 oz) Cans





gaine

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THIS PACKAGE CONTAINS

- Three 60 g (2.11 oz) cans of Men's ROGAINE® Foam (three month supply)
- · Information booklet with complete directions on how to use and obtain best results

USING THE PRODUCT

- To open container: Match arrow on can ring with arrow on cap. Pull off cap.
- · Within the hair thinning area, part the hair into one or more rows to maximize scalp exposure.
- The foam may begin to melt right away on contact with your warm skin. If your fingers are warm, rinse them in cold water first. (Be sure to dry them thoroughly before handling the foam.)
- Hold the can straight upside down and press nozzle to dispense the topical foam product onto your fingers. The total amount of foam applied should not exceed half a capful.
- Using your fingers, spread the foam over the hair loss area and gently massage into scalp and then wash your hands well.
- After each use, close the container to make child resistant by snapping the cap back on to the can.



OPEN CONTAINER





UPSIDE DOWN







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Men's ROGAINE® Foam is for men who have a general thinning of hair on the top of the scalp (vertex only, as shown below). Not intended for frontal baldness or a receding hairline. Men's ROGAINE® Foam has been shown to regrow hair in men with the following degrees of thinning hair or hair loss.

VERTEX



VERTEX



VERTEX



If men have more hair loss or hair loss in a place different than shown above, Men's ROGAINE® Foam may not work





MENS ROGAINE UNSCENTED FORMULA

minoxidil aerosol, foam

Product Information					
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:42002-106		
Route of Administration	TOPICAL	DEA Schedule			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
Minoxidil (Minoxidil)	Minoxidil	50 mg in 1 g			

Inactive Ingredients				
Strength				

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:42002-106-11	1 in 1 PACKAGE				
1		60 g in 1 CAN				
2	NDC:42002-106-13	3 in 1 PACKAGE				
2		60 g in 1 CAN				
3	NDC:42002-106-14	4 in 1 PACKAGE				
3		60 g in 1 CAN				

Marketing Information Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date					
NDA	NDA021812	10/01/2010	manne umg zmu z ute		

Labeler - Johnson & Johnson Healthcare Products, Division of McNEIL-PPC, Inc. (831417154)

Revised: 8/2012

Johnson & Johnson Healthcare Products, Division of McNEIL-PPC, Inc.